UNITED STAT. DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/305,084	05/04/99	SCHNEIDER R	5914-080-999

020583 HM12/0223
PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

EXAMINER	
HARRIS, A	
ART UNIT	**PAPER NUMBER**
1642	08

DATE MAILED: 02/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/305,084	Schneider And Jamal
Examiner	**Group Art Unit**
Alana M. Harris, Ph. D.	1642

☒ Responsive to communication(s) filed on *December 13, 2000.*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-5* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachm nt(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4 and 7*, filed Aug 19, 1999 & Feb 8, 2001.

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I (claim 1-5) in Paper No.6 (filed December 13, 2000) is acknowledged. The traversal is on the grounds that it would not be a serious burden on the Examiner to search Groups I and II at the same time and in the belief that the Examiner incorrectly classified Group II. This is unpersuasive.

The argument that a search encompassing the two Groups is not found persuasive for the reasons set forth in the restriction requirement (Paper No. 5, mailed November 17, 2000). The Examiner does concur with Applicants that the subclass of Group II was incorrect, however this does not warrant removal of the restriction requirement. The correct subclass is 7.6. The method clearly involves two different molecules, an antisense molecule and a ribozyme. As to the question of burden of search, the claims of Groups I and II are classified differently, necessitating different searches in the U.S. Patent shoes. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Clearly different searches and issues are involved in the in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is adhered to.

The requirement is therefore made FINAL.

However, the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed. Method claims limited to the scope of the allowable product claims will be rejoined and examined at the time the product claims are indicated as being allowable.

2. Claims 1-5 are pending.

Claims 6-13 have been canceled.

Claims 1-6 examined on the merits.

Drawings

3. The drawings are objected to because of reasons cited on attached form, PTO-948 completed by draftsman. Correction is required.

Specification

4. The disclosure is objected to because the brief description of the drawings section, specifically Figure 4 on page 19, lines 23-27 of the specification does not contain a separate description of figures 4a-4j. A figure caption for each panel within a figure must be cited within the brief description of the drawings section.

Claim Objections

5. Claim 5 is objected to because the claim contains the recitation " or ribozyme" and Applicants have elected the method of Group I in which the compound is an antisense molecule. The recitation "or ribozyme" must be deleted from the claim.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim 1 is broadly drawn to "A method for treating a cancer, comprising administering a compound ... to a subject in need of such treatment." These claims read on any and all compounds capable of treating any and all cancers. While the specification teaches the administration of compounds, BQ788 and BQ123 to melanocytes and melanoma cell lines, the specification does not teach the administration of any compound to any and all cancers other than melanoma . Many compounds could be administered to a cancer patient in hopes of treatment,

however Applicants have provided just one example of melanoma treatment, exemplified in Example 1 found on pages 47 and 48. Thus the specification is only enabled for the method of treating a melonoma cancer comprising administering BQ788 and BQ123, antagonists of endothelin B receptor. It would require undue experimentation of one skilled in the art to make and use all compounds considered anti-cancer agents that would be possibly effective in the treatment of a cancer.

Likewise, it is well known in the art of cancer treatment that tumors of differing cell types respond differently to a given therapeutic approach, and that a treatment modality that is effective against of a tumor of one given cell type would not necessarily be expected to be effective against tumors of differing histological origin. Cancers of all cell types are not expected, by those of skill in the art, to respond in a similar fashion to the administration of a given class of molecules.

Additionally, the reference by Johnson and Goldin (Cancer Treatment Reviews 2:1-31, 1975) cites that neoplasms of different cell origins respond very differently to a given anti-tumor agent. Table 2 on page 5 is a comparison of the activity spectrum of anti-tumor agents in a variety of human tumors. Note, for example, that methotrexate is effective against acute lymphocytic leukemia, breast, lung, head and neck, cervical and testicular cancers and trophoblastic tumors (and ineffective against gastrointestinal carcinoma, chronic myelogenous leukemia, malignant melanoma and sarcoma), while mitomycin C is effective against gastrointestinal carcinoma (and ineffective against acute lymphocytic leukemia, breast, lung, head and neck, cervical and testicular cancers, trophoblastic tumors, chronic myelogenous leukemia,

malignant melanoma and sarcoma) and hydroxyurea is effective against chronic myelogenous leukemia, malignant melanoma and sarcoma (and ineffective against acute lymphocytic leukemia, breast, lung, head and neck, cervical and testicular cancers, trophoblastic tumors and gastrointestinal carcinoma). Thus, as supported by the Johnson and Goldin reference, one of skill in the art would not expect a suggested anti-tumor agent, such as an neurotoxin, to be effective against neoplasms of differing histological origin. Thus, one of skill in the art could not practice the broadly claimed method, of treating cancers of all cell types, with a reasonable expectation of success.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The recitation "the compound is a mimic" in claim 4 is vague and indefinite. It is not clear in what fashion should the compound resemble or imitate endothelin-1? Should it mock endothelin-1 in structure, activity or binding affinity for the receptor? The metes and bounds cannot be determined.

b. Claim 5 is vague and indefinite in the recitation "molecule". What is the molecule that is claimed to activated ETB? The metes and bounds of the claim cannot be determined. A "molecule" can be anything, such as a peptide, an organic molecule, an inorganic molecule, a DNA fragment, a plastic, a carbohydrate, etc. Applicant's attention is directed to Ex Parte Tanksley (26 USPQ2d 1384) wherein the Board noted that under 35 U.S.C. 112, second paragraph, the claims must be so definite as to allow the comparison with the available art and must also make it possible for the public to determine from the claim what it encompasses. How would one know if the patented claim was being infringed?

c. Claim 5 is vague and indefinite in the recitation "...a molecule that activates ETB." In what manner is this molecule to activate ETB? Hence, the metes and bounds of the claim cannot be determined.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1 and 4 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,382,569 (January 17, 1995)/ Reference AP on IDS. U.S. Patent #5,382,569 discloses novel antagonists of endothelin that are antagonists to an ETB which are useful in treating cancer. These antagonists also mimic endothelin-1, see the abstract.

11. Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Okazawa et al. (Journal of Biological Chemistry 273(20):12584-12592, May 15, 1998)/ Reference DC on IDS. Okazawa discloses a method for treating melanoma cancer comprising administering BQ788, see Figure 2d. This compound is a mimic of endothelin-1, see Figure 1 caption and page 12588, column 1, sentence 2.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 3:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
February 22, 2001

SHEELA HUFF
PRIMARY EXAMINER